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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 94247; 58898/130

In re patent application of

David J. BOVA

Group Art Unit: 1502

Serial No.: 08/368,378

Examiner: J. Venkat

Filed: June 14, 1995

For: NICOTINIC ACID COMPOSITIONS FOR TREATING HYPERLIPIDEMIA

AND RELATED METHODS THEREOF

DECLARATION UNDER 37 CFR §1.132 OF DR. ARTHUR RAINES

RECEIVED

MAY 2 9 1996

Commissioner of Patents and Trademarks Washington, D.C. 20231

GROUP 1500

Sir:

I, Arthur Raines, Ph.D., state and declare that:

- 1. I am a Professor of Pharmacology at Georgetown University in Washington, D.C. My Curriculum Vitae is appended hereto as Exhibit 1.
- I understand that the examiner of the above-captioned application has maintained a rejection of the claims under 35 USC §102(e), as being anticipated by O'Neill et al., U.S. patent No. 5,268,181 (1993) ("the O'Neill patent"). I also understand that the basis of the rejection is that the O'Neill patent discloses a method of treating hyperlipidemia comprising the administration of a single daily dose of a particular niacin composition, preferably, at, or immediately following, the evening meal, but before bedtime. I further understand that the examiner has taken the position that the administration of niacin in the evening or at night is supported by the parent application of the O'Neill patent (Evanstad et al., U.S. patent No. 5,126,145 (1992)["the Evanstad patent"]), which teaches the administration of niacin In particular, the Evanstad patent states that twice daily. "[t]ablets can be scored to permit dasy [sic] breakage into smaller doses for titration up to the standard 750 mg. dose given twice daily." Evanstad patent at column 5, lines 58-60.

- 3. My review of the Evanstad patent revealed that the patent discloses a formulation of a sustained release tablet suitable for use with highly water soluble drugs, which can present formulation problems. The Evanstad patent describes the use of hydroxypropyl methylcellulose and other ingredients to retard the dissolution of water soluble drugs and thus prolong the period of their absorption. Accordingly, the patent is entitled "Controlled release tablet containing water soluble medicament."
- 4. The Evanstad patent indicates that niacin, which is the water soluble agent used as an example of the invention, could be administered twice a day. See the Evanstad patent at column 5, lines 54-62. According to the patent, the stated purpose of the sustained release is to aid in avoiding side effects (which might occur with a standard tablet dosage form where release usually occurs more rapidly and can lead to headache, dizziness, tingling and flushing). At no point in the patent is the issue of a specified time of administration of niacin mentioned, nor is the issue of diurnal variation in lipid biosynthesis addressed; therefore, the timing of the dose to a particularly appropriate part of the day to enhance efficacy is not a component of the Evanstad patent.
- 5. On the other hand, my review of the O'Neill patent revealed that the document specifically addresses the issue of administering the niacin at a specified time period based on the variation in lipid biosynthesis which occurs over the 24 hour time period. See the O'Neill patent at column 2 (lines 45-53), column 3 (lines 15-22) and column 10 (lines 34-37). The O'Neill patent calls for the taking of the sustained release dosage form at some time with or after the evening meal or at bedtime. This will presumably allow for medication levels to be optimal at the time of peak synthesis of serum lipids.
- 6. In summary, the Evanstad patent does not teach or even suggest the O'Neill method of administering niacin at a time of day targeted to coincide with the time at which cholesterol is

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maximally synthesized in the human liver. The once daily, diurnal variation-related dose of niacin described by O'Neill cannot be said to follow from the two dose, diurnal variation-unrelated regimen of Evanstad.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: May 22, 1996

Arthur Raines

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REPORT STATUS FINAL

DATE REPORTED

DMMENTS: "TASTING SPECIMEN"

092070126197744651F

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	RE	FERENCE RANGE	sc
HEMZYAE PEUSZCZSZJA						
ONE AZYMU						in X
GLUCOSE	103	MG/3	PL.	70 - 11	15	
SUDIUM	1 mg	MLIQ.	/1	135 140		
POTASSIUM	3. o	MEQ.		3.5-5.3		
CHUCHIDI.	109	MDQ.	/L.	95-110		
CARBON DIOXIDE CONTENT	25	MEO.	/L	24 - 32	2	
ELLETROLYTE BALAMSE	¥			5-15		
UREA NITROGEN	1.8	MG/I	DH_	7-25		
CHARININE	1.2	mu/)	UL.	0.7-1.4	÷	
BUN/CREATININE RATIO	15	-		8-30		
URIC ACID	త.2	MG.O	JL	4.0 8.5)	
CALCIUM	9.3	MG/3	JAL	8.5-10.	. 6	
PHOSPHORUS, INCREANIC	2.5	HOLD	JL.	2.5-4.5	ï	
PROTEIN, TOTAL	6.4	GM/I	Ų.	6.0-8.5	5	
, ALBUMIN	4.0	GH/:	JI_	3.2-5.5	5	
GLOBULIN	2.4	GH/I	IL.	1.5-3.8	3	
/ 14/5 RATIO	1.7			1.1-2.2	?	
∖ZALCIUM, IONIZED	4.3	HAZI	11_	3.8-4.8	3	
DILIBUREN, TOTAL	0.7	MG/I	نائـ	0.2-1.2	<u> </u>	
ALK PHOS,TOTAL	51	₩/₺		20 14	0	
LACTATE DEHYDROGENASE	156	U/L		0 - 250	;	
AST (SGOT)	21	UZL		0-50		
ALT (SSPT)	30 _	U/L		0 - 55	•	
Section 1 Section 1	4	MG/I	0L	LESS TH	IAN 200	
200 - 239 MO/DL 15 DU	MOLRLINE E	LIGH FOR 20 YEARS	G CLD DR	GREATER		
TRIGLYCERIDES		222, H HG/I		20-160-		
IRON, TOTAL	128.	MCG.	/DL	40 - 15	50	
	w -to	• •				
COMPLETE BLOOD OT & DIFF	5					ΗI
WHITE BLOOD CELLS	~ 5.8	THO	ISAND/CU	- 8.E.MM.	- 10.8	
RED BLOOD CELLS	4.65	MILI	LIONS/CU	.HM.4.40	- 5.80	
HEMOGLOBIN (B)	14.2	GM/I	Ma.	13.8 -	17.2	
HEMATUCRIT	41.8	%		. 41.0 -	50.0	
MCV	90+0	FEM?	FOLITERS	80.0 -	100.0	
MCH	30,6	FIC	ORAMS	27.Q -	33.0	
MCHC:	34-1	% . •		32.0-		
RDW	10.4	UNIT	TS	10.0 -	15.0	
FLATELET COUNT	154	THOU	JSANDZCU	.MM.130 -	- 400	•
NEUTROFHILS	58	%		40 - 75	į	
NEUTROPHILS, ABSOLUTE	- 3,35	THOU	JSANDIZCU	. MM-1.52		
LYMPHOCYTES	32.	%		18 - 47		
-LYHPHOGYTES, ABSOLUTE	1.484			-86.0.MM.		
MINOCYTES	 ق	%		0 - 10		
MONOCYTES. ARSOLUTE	0,33		ISANTI/CII	.MM . 0 . 10	- 1.08	
· · · · · · · · · · · · · · · · · · ·					+ 1. 1.	
EPSINOPHILS	.3	% ,		0 - 6		

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DATE REPORTED

2502921 LAB NO.

DITE COLLEGE - 08/30/90

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PAGE

FES E ORIDA INC 16244 S MILITARY TRAIL 5-590 RAY BEACH, FL 33484

ACCT, NO.

TIME COLLECTED 08/30/90 DATE ENTERED

08/31/90

0800

5:27AM

AGE

** CONFIDENTIAL REPORT ** ₩3 stop 1.60 ROUTE

⊸ Best⊿

FINAL REPORT STATUS

MMENTS:

00

MCHC

RDW:

FLATELET COUNT

NEUTROPHILS

NEUTROPHILS, ABSOLUTE

OUT OF RANGE REFERENCE RESULT TEST UNITS SC (OR INTERPRETATION) RANGE CHEMZYME PLUS/CBC/UA CHEMZYME ***** T GLUCOSE 89 MG/DL 80 - 125SODIUM 1.42 MEQ/L 135-148 4.3 MEQ/L 3.5-5.3 POTASSIUM MEQ.4L CHLORADE 104 95-110 28 24 - 32CARBON DIOXIDE CONTENT MEQ/L 5-15 ELECTROLYTE BALANCE 1.0 MG/DL 7-25 17 UREA NITROGENT MG/JML 0.7-1.4 CREATININE 8-20 BUN/CREATININE RATIO 14 MÖZDL 2.5 - 7.5 URIC ACID 3.4 CALCIUM 7.6 MG/DL 8.5-10.6 MG/III. 2.5-4.5 PHOSPHORUS, INCREANIC 6.9 GM/DL PROTEIN, TOTAL 6.0-8.5 GM/DL 3.2-5.5 3.9 ALBUMIN GLOBULIN GM/DC 3.0 1.5-3.8 1.1-2.2 A/G RATIO 1.3 MGZDL 3.8-4.8-7 CALCIUM, IUNIZED 0.5 MG/OL BILIRUBIN, TOTAL 0.2-1.2 ALKALINE PHUSPHATASE, 20 - 140 TOTAL U/L LACTATE DEHYDROGENASE 126 サノビ 0 - 250ASPARTATE TRANSAMINASE U/L" 0-50 (SGOT) 22 ALANINE AMINOTRANSFERASE UZE (SGPT) 14 0 - 55 F 18 1 MG/DL 0 - 199DESTRABLE ADULT LEVEL FOR CHOLESTEROL IS LESS THAN 200 MG/DL. 20-190 TRIGLYCERIDES MG/DL ···· 40···- 150 MCG/DE IRON, TOTAL HI CECT. PEGIETING OF THE PERSON THOUSAND/CU.MM.3.8 - 10.8 WHITE BLOOD CELLS 3.7 1 HILLIONS/CU:HH:3.90 - 5.20 RED BEOOD CELLS 4106 GMZDE 12.0 - 15.6HEMOGLOBIN (B) 12.3 36.5 ··· 35.0 - 46.0 HEMATOCRIT 59.9 FEMTOLITERS 80.0 - 100.0 MICU PICOGRANS 30.3 27.0 - 33.0 MCH"

INDICATES TESTING SITE SEE REVERSE SIDE

32.0 - 36.0

40 - 75

UNITS 10.0 - 15.0

THOUSAND/CU.MM.130 - 400

THOUSAND/CU.MM.1.52 - 8.10

33.8

10%8

141

50

>> REPORT CONTINUED ON NEXT PAGE <<

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Clinical Laboratories

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"FASTING SPECIMEN" MMENTS:

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	LAB NO. 2502	2756	,			PAGE	1
S-FLORIDA INC	DATE COLLECTED	09/04/90 2				-472	
	TIME COLLECTED		AGE	56	SEX	F	
AY BEACH, FL 33484	DATE ENTERED	09/04/90					
	DATE REPORTED	09/05/90	5:19	PAM			
CONFIDENTIAL REPORT **	REPORT STATUS	FINAL					
00 ROUTE \$4.3 STOP 3.50	090490113	342/632589P					

	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE SC
HOLESTEROL, TOTAL	÷		mG/DL.	0 - 199 MI
DESIRABLE ADULT LEVEL FO	R CHOLEST	TEROL IS LESS	THAN 200 M	G/DL.
RIGLYCERIDES		234 H	MG/DL	20-190 MI
CHOLESTEROL, HIGH DENSITY				"° ∫ . HI
LIPOPROTEIN		35 L	MG/DL	and the second of the second o
DESIRABLE LEVELS OF HUL	CHOLESTER	ROL ARE: MALI		THAN 45 THAN 55
LDL CHOLESTEROL CHOLESTEROL/HDL RATIO	7.06	165 H	MG/DL	LESS THAN 130
CORONARY MEART DIS		g ₁ 1 1 150gg/ 5 14 A 15 44 4 250		
MEN 0.5 AVERAGE		3.43	Sedinauuving Parket 100	, un and a property of the contraction of the contr
AVERAGE 2 X AVERAGE	4	.97 -55	The state of the s	95
3 X AVERAGE	and an action of the second of	1.39 1.27	And the second s	
AVERAGE 2 X AVERAGE	**************************************	7.05	- She is to the second of the	
3 X AVERAGE	1	.04	and discourse and value of some and the second and an analysis of the some and the second and th	
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		- Jugur		

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S-FLORIDA INC

3244 S'MILITARY TRAIL 5-590 Y BEACH, FL 33484

< CONFIDENTIAL REPORT **

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DATE ENTERED

ACCT. NO. 25 4 Best Available Copy
LAB NO. 2502782 DATE 09/07/90 TIME COLLECTED 0800 56 09/07/90 DATE REPORTED 09/08/90 9:03AM REPORT STATUS FINAL 090790121007651675P .

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	sc
A.E.E. PANEL #2 CHOLESTEROL, TOTAL 200 - 239 MG/DL IS	BORDERLINE I	MG/	TEL S OLD OR G	LESS THAN 200 REATER	HI
TRIGLYCERIDES		243 H MG/	TOL.	20-190	MI.
CHOLESTERGE, HIGH DEMO: Lipoprotein	rv —	35 L MG/	Tit.		MI
DESIRABLE LEVELS OF HD	L CHOLESTER	•	GREATER TH	•	er is a super
LDL CHOLESTEROL RATIO	7.71	186 H MG/		LESS_THAN_130	
**************************************	ISEASE RISK	TABLE			
RELATIVE RISK		OL RATIO	May London Company and Advance 20 Advances on the Advances of	and the second of the second o	
MEN 0.5 AVERAGE AVERAGE 3 X AVERAGE	4 9	.43 .97 .55 .39			
WOMEN 0.5 AVERAGE AVERAGE		. 27	Luda	,	
2 X AVERAGE 3 X AVERAGE		.05	y gr		w., y, w.
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e de la german de desta de la companya de la germana de la	An ingge terroppingping say; " An ingge terroppingping say; " An ingge terroppingping say six to the firm from	And the second s	anna a suure suore suomen see ja sega anti santata (see suore suor	The second secon	use syrama
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11/12/90

TIME COLLECTED 830

DATE ENTERED 11/12/90 DATE REPORTED 11/13/90

5:16AM

REPORT STATUS FINAL

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* CONFIDENTIAL REPORT **

_ .AY BEACH, FL 33484

1744 S MILITARY TRAIL S-590

ES-FLORIDA INC

4 00

ROUTE W3 STOP 160

MENTS: "FASTING SPECIMEN"

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	sc
HEMZYME PLUS/CBC/UA		 			
CHEMZYME					MI
GLUCOSE	103	1	1G/DL -	70 - 115	
SOLIUM	144	1	1EQ/L	135 - 148	
POTASSIUM	3.8	1	1EQ/L	3.5 - 5.3	
CHLORIDE	104	1	1EQ/L	95 - 110	
CARBON DIOXIDE CONTENT	28 -	1	1EQ/L	24 - 32	
ELECTROLYTE BALANCE	12			5-15	
UREA NITROGEN	19	f	1G/DL	7 - 25	
CREATININE	1.2	í	1G/IIL	0.7 - 1.4	
BUN/CREATININE RATIO	16		* * ***	8-20	
URIC ACID	4.2	ì	1G/IIL	2.5 - 7.5	
CALCIUM	9.3		1G/DL	8.5 - 10.6	
PHOSPHORUS, INORGANIC	3.5	1	1G/IIL	2.5-4.5	
PROTEIN, TOTAL	6.7			6.0-8-5	
ALBUMIN	3.8	•	SM/IIL	3.2-5.5	
GLOBULIN, TOTAL	2.9			1,5-3,8	
A/G RATIO	1.3			1.1-2.2	
CALCIUM, IONIZED	4.2		1G/DL	3.8-4.8	
BILIRUBIN, TOTAL	0.7	4	IG/DL	0.2 - 1.2	
	81		J/E	20-140	
LACTATE DEHYDROGENASE	147		J/L	0 250	•
AST (SGOT)	weatherman, e		J/L	0-50	
ALI (SGPT)	46		J/L	0 - 55	
	and the same of th		IG/DL	LESS THAN 200)
200 - 239 MG/DL IS BO	RUERLINE	HIGH FOR 20 YE	ARS OLD OR	GREATER	
TRIGLYCERIDES				20-160	
IRON, TOTAL	48		1CG/IL	40 - 150	
COMPLETE BLOOD CT & DIFF	· vinenem marketining	A CONTRACTOR OF THE PARTY OF TH		eren e n en en der de la company de la compa	 MI
WHITE BLOOD CELLS	5 2		HOUGANTIZCH	-MM-3-8 - 10.8	
	4.40			.MM.3.90 - 5.20	
	13.2			12.0 - 15.6	
HEMATOCRIT	39.2	•		35.0 - 46.0	
	89.0			80.0 - 100.0	
MCU			ICOGRAMS	27.0 - 33.0	
nun	30.0		ໍ່າຕໍ່ກໍກັບນຸ່ງອ໌	47.10 7 33.0	

	THOUSAND/CU-MM-3-8 - 10.8
4.40	MILLIONS/CU.MM.3.90 - 5.20
	GM/DL 12.0 - 15.6
39.2	7
	FENTOLITERS-80.0100.0
30.0	FICOGRAMS 27.0 - 33.0
	X 32.0 - 36.0
12.5	UNITS 10.0 - 15.0
142	THOUSAND/CU.MM.130 400
53	% 40 - 75
2.78	THOUSAND/CU-MM-1-52 - 8.10
37	% 18 - 47
1.88	THOUSAND/CU.MM-0.68 - 5.07
6	2 0 - 10
0.28	THOUSAND/CU.MM.0.10 - 1.08
3	% 0 - 6
	4.40 13.2 39.2 89.0 30.0 33.7 12.5 142 53 2.78 37 1.88 6

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INDICATES TESTING SITE SEE REVERSE SIDE T

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PES-FLORIDA INC 16244 S MULITARY TRAIL S-590 DEACH, FL 33484

** CONFIDENTIAL REPORT **

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ROUTE W3

STOP 160

COMMENTS: FASTING

Clinical Laboratories

LAB NO. 2502801 DATECOLLETTES 09/19/90 TIME COLLECTED 0830

DATE ENTERED 09/19/90

AGE 47

7:44AM

PAGE 1

DATE REPORTED 09/20/90 REPORT STATUS FINAL 09199011339/702808P

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	s
CHEMZYME PLUS/CEC/UA				range	
CHEMZYME		•			e de de
GLUCOSE	97	MG/I	י וח	70 - 115	ΜÏ
SODIUM	139	e MEQ.	•	135-148	
POTASSIUM	4.2	MEG		3.5-5.3	
CHLORIDE	103	MEQ		75-110	
CARBON DIOXIDE CONTENT	27	MEQ	_	24 - 32	
ELECTROLYTE BALANCE	9	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	-		
UREA NITROGEN	13	mg/I	<u>. </u>	5-15	
CREATININE	1.2	1.00K		7-25	
BUN/CREATININE RATIO	11	C1837 1		0.7-1.4	
URIC ACID	6.6	MG/I		3-20	
CALCIUM	8.9			.0-8.5	
PHOSPHORUS, INORGANIC	2.8	MG/I		3.5-10.6	
PROTEIN, TOTAL	5.7	MG/I	_	2.5-4.5	
ALBUMIN	4.0	GM/I		.0-8.5	
GLOBULIN	2.7	GM/I		3.2-5.5	
A/G RATIO	1.5	GM/I	Transcon a remark many	.5-3.8	
TALCIUM, IONIZED	4.0	The same of the same	bearing a second of the second	1-2.2	
BILIBUBIN, TOTAL	0.6	MG/1		.8-4.8	
ALK PHOS, TOTAL	· -	MG/I	<u>IL</u> 0	0.2-1.2	
LACTATE DEHYDROGENASE	55	UZE	2	0 - 140	-
AST (SGOT)	125	U/L		- 250	
ALT (SGPT)	21	UZL		-50	
TILT (SOFT)	22	U/L		- 55	
7/00		MG/I		ESS THAN 200	•
200 - 237 MOTEL IS BO	RUERLINE TH		OLD OR GR	EATER	
TRIGLYCERIDES IRON, TOTAL		162 H MG/D		0-160	
THOM, INIME	102	MCG/		0 - 150	
COMPLETE DI CON OT A TAR	a comment		The second second	-	-
COMPLETE BLOOD CT & DIFF			And the second of the second o	there was an authorities produced that in our months in the	MÏ
WHITE BLOOD CELLS	J.Q.	A LEAD TO SEE THE PARTY OF	BAND/CU.MM	3.8 - 10.8	
RED BLOOD CELLS	4.49		IONS/CU.MM		
HEMOGEOBEN (B)	23.8			3.8S= 17.2	***************************************
HEMATOCRIT	7	40.1 E 22	4	1.0 - 50.0	<u></u>
	THE RELEASE FOR				
MCH	30.6	PICO	GRAMS 2	7.0 - 33.0	
	34.3	Non-tendent of the Control of the Co		2.0 = 36.0	
ROW.	11.8	UNIT		0.0 - 15.0	
PLATELET COUNT	175			130 - 400	
NEUTROPHILS	51	X			
NEUTROPHILS, ARSOLUTE	2.34			0 - 75	
LYMPHOCYTES	39	And the second s		1.52 - 8.10	
LYMPHOCYTES, ARSOLUTE	1.93	and the state of the second state of the second state of the second seco		3 - 47	
A-MONOCYTES	and the second s	THOUS	פעמה לחי עם	3.68 - 5.07	
HONOCYTES, ABSOLUTE	pro on Mandellanderskim !! ?!		9	1.0	
FOSINOPHII S	0.31	יודים	SAND/CIT. MM.	0.10 - 1.08	
	O SECTION OF THE PARTY AND ADDRESS OF THE PART	7.	O	· é	l
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